

for serving on a Scientific Advisory or Data Safety Monitoring board for ArgenX, Belgium. Dr. Nobile-Orazio has received personal compensation in the range of \$500-\$4,999 for serving on a Scientific Advisory or Data Safety Monitoring board for LFB, France. Dr. Nobile-Orazio has received personal compensation in the range of \$500-\$4,999 for serving on a Scientific Advisory or Data Safety Monitoring board for Roche, Switzerland. Dr. Nobile-Orazio has received personal compensation in the range of \$500-\$4,999 for serving on a Scientific Advisory or Data Safety Monitoring board for CSL Behring. Dr. Nobile-Orazio has received personal compensation in the range of \$500-\$4,999 for serving on a Scientific Advisory or Data Safety Monitoring board for Janssen, USA. The institution of Dr. Nobile-Orazio has received research support from Takeda/Shire. Dr. Peric has received personal compensation in the range of \$5,000-\$9,999 for serving as a Consultant for ArgenX. Dr. Peric has received personal compensation in the range of \$500-\$4,999 for serving as a Consultant for Mylan. An immediate family member of Dr. Katzberg has received personal compensation for serving as an employee of Sanofi Genzyme. Dr. Katzberg has received personal compensation in the range of \$500-\$4,999 for serving as a Consultant for ArgenX. Dr. Katzberg has received personal compensation in the range of \$500-\$4,999 for serving as a Consultant for UCB. Dr. Katzberg has received personal compensation in the range of \$5,000-\$9,999 for serving on a Scientific Advisory or Data Safety Monitoring board for Octapharma. Dr. Katzberg has received personal compensation in the range of \$500-\$4,999 for serving on a Speakers Bureau for UCB. Mrs. Cadour has nothing to disclose. Miss Van de Walle has received personal compensation for serving as an employee of argenx bv. Mrs. Van Hooissen has received personal compensation for serving as an employee of argenx. Mr. Jacquemyn has received personal compensation for serving as an employee of argenx. Dr. Van de Steen has received personal compensation for serving as an employee of argenx. Dr. Van de Steen has stock in argenx. Dr. van der Pol has nothing to disclose.

### **Vibrance-mg: Clinical Trial of Nipocalimab in Pediatric Myasthenia Gravis**

Sindhu Ramchandren, Shawn Black, Hong Sun

#### **Objective**

We describe an open-label study of nipocalimab to determine the effect of nipocalimab in pediatric participants with gMG.

#### **Background**

Nipocalimab is a high affinity, fully human, aglycosylated, effectorless IgG1 anti FcRn monoclonal antibody that targets the neonatal Fc receptor (FcRn) with high affinity, thereby lowering IgG pathogenic antibodies in autoimmune disease. Data from Vivacity-MG, a Phase 2, multicenter, randomized, double-blind, placebo-controlled study of nipocalimab demonstrated safety, tolerability, and efficacy of nipocalimab in adult generalized myasthenia gravis (gMG) (clinicaltrials.gov NCT03772587).

#### **Design/Methods**

This global study will enroll at least 12 participants, aged 2 to <18, with a diagnosis of gMG and an insufficient clinical response to ongoing, stable standard-of-care therapy, as reflected by a Myasthenia Gravis Foundation of America (MGFA) Class of IIa/b through IVa at screening. Participants must have a positive serologic test for either acetylcholine receptor or Muscle Specific Tyrosine Kinase pathogenic autoantibody. The study will consist of a screening period of up to 4 weeks, a 24-week open-label Active Treatment Phase where participants will receive nipocalimab intravenously every two weeks, and a Long-term Extension phase; after last dose, a safety follow-up assessment will be conducted at 8 weeks. The primary outcome is the effect of nipocalimab on total serum IgG, safety and tolerability, and PK in pediatric participants with gMG.

#### **Results**

Study enrollment will begin in 2022.

#### **Conclusions**

The vibrance-mg study will assess the PK/PD, safety and activity of Nipocalimab in pediatric gMG.

**Disclosure:** Dr. Ramchandren has received personal compensation for serving as an employee of Janssen Pharmaceutical Companies of Johnson & Johnson. Dr. Ramchandren has a non-compensated relationship as a Scientific Advisory Board Member with CMT Research Foundation (CMTRF) that is relevant to AAN interests or activities. Mr. Black has received personal compensation for serving as an employee of Janssen. Mr. Black has stock in Janssen. Dr. Sun has received personal compensation for serving as an employee of Janssen.

### **Vivacity MG Phase 3 Study: Clinical Trial of Nipocalimab Administered to Adults With Generalized Myasthenia Gravis**

Sindhu Ramchandren, Panna Sanga, Michel Burcklen, Hong Sun

#### **Objective**

We describe Vivacity-MG3, our pivotal Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, Pharmacokinetics (PK), and Pharmacodynamics (PD) of Nipocalimab Administered to Adults With gMG (NCT04951622).

#### **Background**

Nipocalimab is a high affinity, fully human, aglycosylated, effectorless IgG1 anti FcRn monoclonal antibody that targets the neonatal Fc receptor (FcRn) with high affinity, thereby lowering IgG pathogenic antibodies in autoimmune disease. Data from Vivacity-MG, a Phase 2 randomized placebo-controlled study of nipocalimab in adult generalized myasthenia gravis (gMG), demonstrated safety, tolerability, and efficacy of nipocalimab (clinicaltrials.gov NCT03772587).

#### **Design/Methods**

This global study will enroll approximately 180 participants with gMG, aged 18 and older, with an insufficient clinical response to ongoing, stable standard-of-care therapy, as reflected by a Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of  $\geq 6$  at screening and baseline, and a Myasthenia Gravis Foundation of America (MGFA) Class of IIa/b–IVa/b at screening. The study will consist of a screening period of up to 4 weeks, a 24-week double-blind placebo-controlled phase where participants will be randomly assigned in a 1:1 ratio to receive either placebo or nipocalimab intravenously every two weeks, and an open label extension phase of variable duration. The primary outcome is the average change in MG-ADL score from baseline to weeks 22, 23 and 24 of the double-blind placebo-controlled phase.

#### **Results**

Study enrollment began in July 2021 and is ongoing.

#### **Conclusions**

The ongoing Vivacity MG Phase 3 study will assess the efficacy, safety, and PK/PD of Nipocalimab in adult gMG.

**Disclosure:** Dr. Ramchandren has received personal compensation for serving as an employee of Janssen Pharmaceutical Companies of Johnson & Johnson. Dr. Ramchandren has a non-compensated relationship as a Scientific Advisory Board Member with CMT Research Foundation (CMTRF) that is relevant to AAN interests or activities. Panna Sanga has received personal compensation for serving as an employee of Janssen Research & Development. Panna Sanga has stock in Johnson & Johnson. Michel Burcklen has received personal compensation for serving as an employee of Actelion Pharmaceuticals, a Janssen pharmaceutical company of Johnson & Johnson. Michel Burcklen has received stock or an ownership interest from Johnson & Johnson. Dr. Sun has received personal compensation for serving as an employee of Janssen.

### **Response of Sjogren-related Small Fiber Neuropathy to rituximab**

Anita Venkatesh, Suraj Muley

#### **Objective**

Small fiber neuropathy typically presents as loss of temperature and pain sensation and may be associated with other autonomic symptoms. Sjogren's-related ganglionopathy can selectively affect small fibers. Current treatment options for small fiber neuropathy secondary to

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## Vibrance-mg: Clinical Trial of Nipocalimab in Pediatric Myasthenia Gravis

Sindhu Ramchandren, Shawn Black and Hong Sun

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